

# APPARATUS FOR DELIVERING AND DEPLOYING AN EXPANDABLE STENT WITHIN A BLOOD VESSEL

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of the filing date of International Application PCT/EP2003/008795, filed August 7, 2003, which claims priority from European application 02017696.2, filed August 7, 2002.

## FIELD OF THE INVENTION

[0002] The present invention relates to an apparatus ~~a system~~ for delivering and deploying an expandable a stent into within a blood vessel for use ~~e.g. by a physician in a well known manner for supporting and/or in~~ reinforcing the vessel walls and maintaining the vessel in an open, unobstructed condition. ~~It is well known in the prior art that the stent can be covered and secured in a catheter by a sheath during tracking and delivery in a blood vessel.~~

## BACKGROUND OF THE INVENTION

[0003] ~~Furthermore, it is known that the sheath is retracted before positioning the stent within the vessel. A stent delivery system according to US-United States Patent No. 6,168,617 discloses a stent delivery system comprising comprises a catheter with having a balloon for inflating a stent, which is covered having during delivering by a sheath. The sheath is axially moveable on the shaft of the catheter and can be retracted in the proximal direction by pull back means.~~

[0004] ~~US-United States Patent No. 5,113,608 discloses a stent delivery device which comprises comprising a hydraulically actuated retractable sheath. Specifically, a pressurising fluid is either supplied by an inflation volume to a portion of a piston housing (or is withdrawn from a portion of the piston housing), thereby actuating a the piston and causing the sheath to retract. As the piston moves the sheath is retracted.~~

[0005] ~~It is the object of the invention~~ In view of the above, it would be desirable to provide an improved stent delivery system with having a protection sheath on the stent to simplify handling of the stent wherein its handling is simplified.

~~The object is achieved by the features of the claims.~~

~~In order to achieve the object, the invention is based on the following basic ideas:~~

### SUMMARY OF THE INVENTION

[0006] In view of the foregoing, it is an object of the present invention to provide an improved stent delivery system having a protection sheath on the stent to simplify handling of the stent.

[0007] These and other objects of the present invention are accomplished by providing a device for retracting the sheath ~~that~~ is coupled with a fluid pressure device for ~~the~~ inflation and deflation of expandable ~~means (balloon)~~ for deploying the stent. A pressurised fluid, ~~e.g. a liquid or gas~~, is supplied from the fluid pressure device to the retraction device ~~and causes to cause~~ the retraction of the sheath. After or during the retraction of the sheath, the pressurised fluid in is directed to the expandable ~~means~~ balloon for expansion and deployment of the stent. ~~According to the invention, the~~ The expansion of the stent is controlled by the position of the piston within the a cylinder. Thus, an automatic inflation of the expandable means after orduring retraction of the sheath can be achieved.

~~The invention has the following advantages:~~

[0008] The protection sheath is withdrawn by activating the fluid pressure device, which also controls the expansion of the stent ~~by means of the expansion means~~. Advantageously, the protection sheath prevents problems associated with bi-stable stent designs, such as stent-loss and pop-open. Furthermore, stent loss and pop open by using bi-stable stent designs such as Biflex stents do not occur. There is also Additionally, there is no flaring of stainless steel stents and no significantly increased profiles (sheath thickness 0,01 to 0,02 mm). If a drug coated stent is used, there will be substantially no drug loss no drug will be lost during handling.

### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0009] Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

[0010] FIGS. 1a and 1b are a schematic diagrams of an embodiment of the apparatus for delivering and deploying an expandable stent within a blood vessel, according to the present invention;

[0011] FIG. 2 is a cross-sectional view of another embodiment of the apparatus for delivering and deploying an expandable stent within a blood vessel, according to the present invention;

[0012] FIGS. 3-10 are cross-sectional views of the apparatus of FIG. 2, showing steps of the method of operation of the apparatus;

[0013] FIG. 11 is a cross-sectional view of a further embodiment of the apparatus for delivering and deploying an expandable stent within a blood vessel, according to the present invention; and

[0014] FIGS. 12-19 are cross-sectional views of the apparatus of FIG. 11, showing steps of the method of operation of the apparatus.

~~Fig. 1a is a schematic illustration of a first inventive embodiment,~~

~~Fig. 1b shows the partial proximal end of the cylinder 15 in Fig. 1a after retraction of the sheath,~~

~~Fig. 2 is a schematic illustration of a second inventive embodiment,~~

~~Figs 3-10 show steps of the method of operation of the second inventive embodiment,~~

~~Fig. 11 is a schematic illustration of a third inventive embodiment, and~~

~~Figs 12-19 show steps of the method of operation of the third inventive embodiment.~~

## DETAILED DESCRIPTION OF THE INVENTION

[0015] ~~In the first inventive embodiment of Fig. Referring to FIG. 1a, sheath 1 is arranged on stent 2 and supported by expandable means 3, preferably an inflatable balloon 3. The arrangement 1, 2 and 3 is sheath, stent and balloon are supported by a catheter (not shown) and inserted into a blood vessel. Furthermore, a sheath retraction device (5 to 9, 11 and 13 to 15) and a fluid pressure device (11 to 14) are connected with the sheath, stent and balloon arrangement 1 to 3 by a wire 4 and a tube 10, respectively. Particularly, The wire 4 connects the sheath 1 with a first piston 5 disposed in a cylinder 15 comprising a cylinder housing 9. A Hook 6 is connected at the proximal side of the piston 5.~~

[0016] ~~The Cylinder 15 further comprises a floating second piston 7 with having an opening 18, which can be penetrated by the hook 6. The floating piston 7 closes an outlet 17 in the cylinder 15. The tube 10 connects the expandable means balloon 3 with a tube 16~~

mounted at the outlet 17 of the cylinder 15. A tube 14 is connected to an inflation/deflation device schematically shown as double-arrow 13 at the one end and via a unidirectional valve (check valve) 11 with the cylinder 15 at the other end. Furthermore, the tube 14 is connected via a unidirectional valve (check valve) 12 with the tube 10.

~~The first inventive embodiment operates as follows:~~

[0017] In the arrangement of Fig. 1a the operation, expandable means balloon 3 is in a deflated state and the sheath 1 covers the stent 2. The floating second piston 7 is positioned so that the opening 17 of the cylinder housing 9 and, thus, the tube 16 are closed. An operator such as a (physician) applies pressure from the inflation/deflation device 13 to the tube 14. The pressure shuts the unidirectional valve 12 and opens the unidirectional valve 11. Thus, the pressurised fluid flows into the cylinder 15 and shifts the first piston 5 with the wire 4 and the sheath 1 in the proximal direction, i.e. the such that sheath 1 is retracted from the stent 2. The pressure necessary for moving the piston 5 preferably is very low.

[0018] When the first piston 5 reaches the floating second piston 7, the proximal end of the wire 4 with the hook 6 penetrates the opening 18 in the piston 7, and the piston 5 moves the forces piston 7 to move proximally the proximal end of the cylinder 15. Thereby At the proximal end of cylinder 15, the hook 6 engages the hook holder 8 wherein such that the piston 5, with the wire 4 and the sheath 1 is are fixed at the proximal end, as depicted in FIG. 1b. This fixed position of the pistons 5 and 7 is shown in figure 1b. In this position, the sheath is completely removed (not shown) from the stent 2, and the outlet 17 of the cylinder 15 is open towards the cylinder chamber.

[0019] In operation ~~this manner~~, the pressurized fluid from the inflation/deflation device 13 flows via the tube 14 and into the left side of the cylinder 15. From the cylinder, the pressurized fluid flows through the outlet 17, the tube 16 and the tube 10 to the expandable means balloon 3, inflates it and deploys the stent 2. The pressure is applied until a required predetermined stent diameter is achieved ~~reached~~. Then, the operator applies a vacuum suction from the inflation/deflation device 13 via the unidirectional valve 12 and the tube 10 to the expandable means balloon 3. During this suction, the unidirectional valve 11 is closed. At the end of the stent delivery and deployment process, the catheter ~~with the expandable means and the sheath~~ is removed from the blood vessel and the stent remains in the desired position within the blood vessel.

[0020] Referring to FIG. 2, according to another embodiment of the invention, ~~In the second inventive embodiment of Fig. 2 as in Fig. 1a, a protective cover sheath 101 is arranged on a stent 102, which is supported by an expandable balloon means 103 being an inflatable balloon. As in Fig. 1a, the arrangement 101, 102 and 103 is~~ Similar to the embodiment of FIG. 1, sheath 101, stent 102 and balloon 103 are supported by a catheter (not shown), which ~~and~~ is inserted into a blood vessel. Sheath 101, stent 102 and balloon 103 are The arrangement 101, 102 and 103 is connected via a pull-wire 104 to a cylinder-piston arrangement (105, 106, 108, 110, 110a, 112 and 114).

[0021] With further reference to FIG. 2, ~~t~~The cylinder-piston arrangement is connected to an inflation/deflation device that is schematically shown as ~~an~~ arrow 113. A ~~P~~piston 105 with a connector ball 106 is arranged in the cylinder ~~445~~ at its distal end 115a. The ~~W~~wire 104 is fixed at the piston. Receiving socket 108 is located a ~~At~~ the proximal end 115b of ~~the~~ cylinder 115, a receiving socket 108 is located, into which ~~T~~the connector ball engages receiving socket 108 when the piston arrives at the proximal end, ~~i.e. the right hand side in Fig. 2, of the cylinder 115. Furthermore, T~~the cylinder-piston arrangement further comprises a unidirectional valve 112, fluid pressure lines 114, 110, 110a and ~~an~~ inlet/outlet 117 ~~as connection to the for~~ inflation/deflation device 113.

[0022] Referring to FIGS. ~~With respect to Figs 3-10, the steps of operation of the second inventive embodiment of FIG. 2 are shown now described. In the second and subsequently in the third inventive embodiment, the fluid F is illustrated by black colour.~~

[0023] Referring to FIG. 3 ~~Firstly, vacuum from the inflation/deflation device 113 is employed applied (Fig. 3) in order to purge air from the catheter and the sheath retraction apparatus. In this state, the unidirectional valve 112 is opened and all parts of the apparatus are in connection with the vacuum. After removing the air from the apparatus, pressurized fluid F (e.g., liquid) is introduced from the inflation/deflation device 113 via the inlet/outlet 117. The fluid is shown in black in the figures for illustrative purposes only.~~

[0024] Referring to FIG. 4, ~~t~~The force of pressurized fluid F shuts ~~the~~ unidirectional valve 112, and fluid F enters ~~the~~ cylinder 115 at its distal end 115a behind ~~the~~ piston 105 (~~i.e. at the left hand side of the piston in Fig. 4~~). Referring to FIG. 5, ~~t~~The force of pressurized fluid F moves ~~the~~ cylinder 105 in the proximal direction ~~wherein such that the~~ wire 104 retracts ~~the~~ protective cover sheath 101 from ~~the~~ stent 102 (~~arrow A in Fig. 5~~). During this procedure, the liquid preferably is prevented from entering the catheter and the

~~expandable means 103~~ balloon.

[0025] Referring to FIG. ~~As shown in Fig. 6~~, after arrival of ~~the~~ piston 105 at the proximal end 115b of ~~the~~ cylinder 115, ~~the~~ cover sheath 101 is completely removed from ~~the~~ stent 102, ~~the~~ connector ball 106 is engaged in ~~the~~ receiving socket 108, ~~and a~~ Also, opening 110a, which penetrates the cylinder wall to the fluid pressure line 110, is opened. The pressurized fluid ~~F from the inflation/deflation device 113 via the line 114 and the cylinder 115 enters the line 110 and inflates the~~ balloon expandable means 103, as depicted in FIG. 7 ~~(Fig. 7)~~.

[0026] Referring to FIG. 8, ~~tThe expandable means (balloon) 103 expands and the stent 102 is deployed and contacts the wall of the blood vessel (Fig. 8). Thereafter, the fluid is withdrawn and a vacuum is again applied by means of the inflation/deflation device 113 to deflate the balloon while the piston 105 and the cover sheath 101 remain fixed, as depicted in FIG. 9. (Fig. 9). Referring to FIG. 10~~ In Fig. 10, the system is fully purged of fluid (e.g. liquid) and ~~the~~ balloon 103 can be re-inflated if necessary, or the ~~expandable means~~ balloon and sheath may be removed from the blood vessel while the stent remains in the desired position within the blood vessel.

[0027] Referring to FIG. ~~Fig. 11~~, a further embodiment of the present invention is ~~described~~ shows a third inventive embodiment, which differs from the first and second embodiment in the structure of the cylinder-piston arrangement. A ~~T~~ two-position valve 207 is located in the cylinder 215, wherein, the valve 207 abuts via a spring 207a disposed at the proximal end 215b (right hand side in Fig. 11) of the cylinder 215. In the illustrated embodiment position shown in Figs 11 to 14, the valve 207 shuts two a pair of channels 216a, 216b, which penetrate the wall of the cylinder 215;

[0028] C ~~channel 216a connects a fluid pressure line 214 from the fluid pressure device 213 with a fluid pressure line 210, which supplies~~ applies the fluid pressure to ~~the expandable means (balloon) 203. When the piston 205 starting from the space 215a at the distal end of the cylinder 215 arrives is disposed at the two-position valve 207, it pushes the valve proximally (to the right in Fig. 15) and opens the channels 216a and 216b. Thus, pressurized fluid F from the inflation/deflation device 213 enters the balloon 203 via the line 214, the channels 216a and 216b and the line 210 (Figs 15 to 17).~~

[0029] Referring to FIGS. 12-19, ~~tThe steps of the method of operation of the third inventive embodiment of FIG. 11 are now described shown with respect to Figs. 12-19.~~

**[0030]** ~~Initially~~Before operating, a vacuum is applied in order to purge air from the catheter and the sheath retraction apparatus by means of ~~the~~inflation/deflation device 213. ~~Thereby~~Specifically, the unidirectional valve 212 is opened and ~~the~~unidirectional valve 211 is closed so that space 215a at the distal end of ~~the~~cylinder 215 ~~at the left hand side of the piston 205~~remains open (~~Fig. 12~~). ~~Referring to FIG. 13~~In Fig. 13, while unidirectional valve 212 and channels 216a and 216b are closed, pressurized fluid F from ~~the~~inflation/deflation device 213 enters ~~the~~space 215a of ~~the~~cylinder 215 behind ~~the~~piston 205 via ~~the~~line 214 and ~~the~~unidirectional valve 211, ~~while the unidirectional valve 212 and the channels 216a and 216b are closed~~. Thereafter, ~~the~~piston 205 moves in the proximal direction, ~~(to the right in Fig. 14) and withdraws the~~ thereby retracting protective cover sheath 201 from the stent 202 in the direction of arrows A, as depicted in FIG. 14 (~~Fig. 14~~).

**[0031]** Referring to FIG. 15, ~~a~~After the protective cover sheath 201 is fully retracted, ~~the~~piston 205 pushes ~~the~~valve 207 into an open position against the force of ~~the~~spring 207a ~~into an open position~~, and the connection between ~~the~~line 214 and ~~the~~line 210 via ~~the~~channels 216a and 216b is opened (~~Fig. 15~~). Referring to FIG. 16, ~~As shown in Fig. 16~~, pressurized fluid F flows via ~~the~~line 214, ~~the~~channels 216a and 216b and ~~the~~line 210 to ~~the~~balloon 203. While ~~the~~unidirectional valve 211 remains open and pressurized fluid F acts against ~~the~~piston 205 ~~and pushes it to the right in Fig. 17~~, ~~the~~two-position valve 207 remains in ~~its~~the open position. Referring to FIG. 17, ~~The~~balloon 203 expands in the direction of arrows B and the stent is deployed such that it (~~Fig. 17~~) ~~and~~contacts the wall of the blood vessel (~~not shown~~).

**[0032]** Thereafter, vacuum is again applied from ~~the~~inflation/deflation device 213 and ~~the~~balloon 203 deflates in the direction of arrows C, as depicted in FIG. 18 (~~Fig. 18~~). The unidirectional valve ~~211~~is closed and the pressurized fluid behind ~~the~~piston 205 acts on ~~the~~piston 205 such that ~~the~~piston 205 and ~~the~~sheath 201 remain fixed (~~Fig. 18~~). Referring to FIG. 19, ~~In the final state shown in Fig. 19~~, the catheter is fully purged and the balloon can be re-inflated if necessary. The pressurized fluid F holds ~~the~~two-position valve 207 open and locks ~~the~~sheath 201 in the retracted position. If the retraction apparatus will be used one time only, it can be removed. However, ~~if~~ the retraction apparatus will be re-used, ~~the~~fluid F is purged from ~~the~~cylinder 215 by opening ~~the~~unidirectional valve 211 and pulling ~~the~~piston 205 to ~~the~~distal end 215a.

**[0033]** The fluid pressure for operating the retraction device and the expandable means

can be controlled in such a manner that the retraction device and the ~~expandable~~  
~~means~~balloon work concurrently or sequentially, ~~e.g.~~ in order to control the correct position  
of the stent.

[0034] According to a preferred implementation of the invention, ~~It is an essential~~  
~~feature of the invention that~~ the retraction of the sheath 1, 101 and 201, respectively, namely  
~~at the end of the retraction step,~~ automatically controls the deployment (~~expansion~~) of the  
stent 2, 102 and 202, respectively. Therefore, ~~a~~An operator ~~can~~may easily deploy a the  
stent ~~with a protection sheath simply~~ by activating the inflation/deflation device.



## ABSTRACT OF THE DISCLOSURE

[0035] ~~An improved Apparatus for delivering and deployment of an expandable stent~~  
~~with having~~ a protection sheath within a blood vessel is provided. The system apparatus  
comprises a fluid pressure device ~~which that~~ is coupled with a retraction device for the  
protection sheath, wherein such the stent is automatically deployed by the fluid pressure  
device that after retraction of the protection sheath ~~the stent is automatically deployed by the~~  
~~fluid pressure device. The advantage of the invention is an easy and simple operation of the~~  
~~apparatus.~~